

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 61612 PCT	FOR FURTHER ACTION	See item 4 below
International application No. PCT/US2004/023146	International filing date (<i>day/month/year</i>) 19 July 2004 (19.07.2004)	Priority date (<i>day/month/year</i>) 18 July 2003 (18.07.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant THE JOHNS HOPKINS UNIVERSITY		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | |
|---|---|
| <input checked="" type="checkbox"/> Box No. I | Basis of the report |
| <input type="checkbox"/> Box No. II | Priority |
| <input checked="" type="checkbox"/> Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> Box No. VI | Certain documents cited |
| <input type="checkbox"/> Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

	Date of issuance of this report 23 January 2006 (23.01.2006)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Yoshiko Kuwahara
Facsimile No. +41 22 740 14 35	Telephone No. +41 22 338 90 90

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

REC'D 14 APR 2005

PCT
WIPO

PCT

To:
STEVEN M. JENSEN
EDWARDS & ANGELL, LLP
P.O. BOX 55874
BOSTON, MA 02205

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year)

12 APR 2005

Applicant's or agent's file reference

61612 PCT

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US04/23146

International filing date (day/month/year)

19 July 2004 (19.07.2004)

Priority date (day/month/year)

18 July 2003 (18.07.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61N 1/18 and US Cl.: 607/2

Applicant

THE JOHNS HOPKINS UNIVERSITY

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Authorized officer

Angela Sykes

Telephone No. (703)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US04/23146

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US04/23146

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 40-67

because:

☒ the said international application, or the said claim Nos. 40-67 relate to the following subject matter which does not require an international preliminary examination (*specify*):

Claims 40-67 have not been examined because they are related to non-statutory subject matter. Specifically, the claiming of structures being in contact with or implanted within the body amounts to an inferential recitation of the body, which renders these claims non-statutory.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____ are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/23146

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Claims 3, 6-9, 11, 19, 22, 24, 33-36, 39 YES

Claims 1-2, 4-5, 10, 12-18, 20-21, 23, 25-32, 37-38 NO

Inventive step (IS)

Claims NONE YES

Claims 1-39 NO

Industrial applicability (IA)

Claims 1-39 YES

Claims NONE NO

2. Citations and explanations:

Please See Continuation Sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US04/23146

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

V. 2. Citations and Explanations:

1. Claims 1-2, 4, 10, 15-18, 20, 23, 25-28, 32 and 37-38 lack novelty under PCT Article 33(2) as being anticipated by KIM et al. (US 5,514,175). KIM et al. discloses an auricular stimulator, which electrically stimulates auricular points associated with the vagus nerve to treat pain, anxiety and dysfunction of the neural pathways. One such dysfunction was Atlanta-axial tilt with nausea. The stimulation received by the patient with Atlanta-axial tilt, was relieved of nausea and vertigo, as well as her other symptoms. Since the device can be used to treat vertigo, and motion sickness can cause vertigo, the device can inherently be used in the treatment of by motion sickness.

2. Claims 1-2, 5, 12-14 and 31 lack novelty under PCT Article 33(2) as being anticipated by SWOYER et al. (US 6,754,536 B2). SWOYER et al. discloses a GI tract stimulator and monitor IMD. This device can be used in treatment of gastric mobility disorders, such as gastroparesis, which can cause nausea and vomiting.

3. Claims 1-2, 5, 12, 14, 20-21 and 29-30 lack novelty under PCT Article 33(2) as being anticipated by BEN-HAIM et al. (US 6,571,127 B1). BEN-HAIM et al. discloses a method for increasing the mobility of the GI tract. The electrical pacing of the GI tract is also practiced in combination with electrical stimulation of the vagus nerve. The stomach, through electrical stimulation, can be desensitized, which is useful in the treatment of nausea, pregnancy related nausea and reflex vomiting.

4. Claims 3 and 11 lack an inventive step under PCT Article 33(3) as being obvious over KIM et al. (US 5,514,175). KIM et al. discloses the device substantially as claimed but fails to teach placement of electrodes on the neck or the use of adhesive on the electrodes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use adhesive electrodes and stimulate near the neck since it is known that adhesive electrodes prevent the electrodes from shifting and the vagus nerve runs through the neck and stimulation of the vagus nerve can occur anywhere along its length.

5. Claims 34-35 lack an inventive step under PCT Article 33(3) as being obvious over BEN-HAIM et al. (US 6,571,127 B1). BEN-HAIM et al. discloses the device substantially as claimed but fails to teach the treatment of a chemotherapy patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use this device to treat a patient undergoing chemotherapy, since it is known that chemotherapy can disrupt the GI tract by causing side effects of nausea and vomiting. Therefore, since chemotherapy disrupts normal GI activity, it would be obvious to treat chemotherapy patients with electrical stimulation in order to allow their GI functions to return to normal.

6. Claims 6-9, 19, 22, 24, 33 and 39 lack an inventive step under PCT Article 33(3) as being obvious over KIM et al. (US 5,514,175) in view of POLICKER et al. (US Patent Publication 20040059393 A1). KIM et al. discloses the device substantially as claimed but fails to teach the use of magnetic induction. It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize magnetic induction, since POLICKER et al. teaches that it is well known in the art to communicate with magnetic induction or radio frequency signals.

7. Claim 36 lack an inventive step under PCT Article 33(3) as being obvious over BEN-HAIM et al. (US 6,571,127 B1), as applied to

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US04/23146

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

claims 34-35, in view of POLICKER et al. (US Patent Publication 20040059393 A1). KIM et al. discloses the device substantially as claimed but fails to teach the use of magnetic induction. It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize magnetic induction, since POLICKER et al. teaches that it is well known in the art to communicate with magnetic induction or radio frequency signals.

8. Claims 1-39 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.